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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,988	07/15/2002	Jurgen Markl	GKS-102.0(7911/86349)	2621

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WELSH & KATZ, LTD
120 S RIVERSIDE PLAZA
22ND FLOOR
CHICAGO, IL 60606

EXAMINER

NOAKES, SUZANNE MARIE

ART UNIT PAPER NUMBER

1653

DATE MAILED: 01/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/049,988		MARKL ET AL.	
	Examiner		Art Unit	
	Suzanne M. Noakes, Ph.D.		1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24, 25, 32-35 and 38-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24, 25, 32-35 and 38-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9-23-2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 24, 25, 32-35 and 38-42 are pending and under examination. The amendments filed September 23, 2005 are acknowledged.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on September 23, 2005 has been considered by the examiner.

Withdrawal of Rejections/Objections

3. The objection to the specification is withdrawn because: (a) Applicants have submitted an abstract of the disclosure and (b) Applicants have amended the layout of the specification to comply with the guidelines provided in 37 CFR 1.77(b).
4. The rejection of claims 24, 25, 32-35 and 38-42 under 35 U.S.C. 101 are withdrawn in view of the amendment to the claims reciting isolated.

Maintained Rejections/Objections

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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6. Claims 24, 25, 32-35 and 38-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The details of the rejection can be found in Sections 10-11 of the previous Office action.

Claim Rejections - 35 USC § 102

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Gebauer et al. (1994 - Cited on the IDS submitted on 15 July 2003). The details of the rejection can be found in Sections 10 of the previous Office action.

9. Claims 38-42 are rejected under 35 U.S.C. 102(b) as being anticipated by the 1995 Sigma Product Catalog. The details of the rejection can be found in Sections 11 of the previous Office action.

Response to Arguments

35 USC § 102

9. Applicant's arguments filed September 23, 2005 have been fully considered but they are not persuasive. Applicants traverse the rejection and contend that Gebauer et al. do not teach the isolation and purification of homogenous subunits of KLH2 but only an analysis to determine the formerly unknown subunit organization of KLH2. Furthermore, it is reasoned that the way in which Gebauer et al. conducted their experiments, e.g. treating whole KLH2 by limited proteolysis in order to separate each

domain of KLH2 into each of its respective a-h domains, would necessarily result in fragments which would represent a mixture of different sequences that were not homogeneous or highly purified.

The examiner respectfully disagrees on the first point, that Gebauer et al. did not isolate the respective subunits. Isolation is separate from purification, and purification is not at issue because it is not stated in the claims. Isolated is deemed as being taken out of its natural state, thus a skilled artisan need only break open a cell which contains whole KLH (e.g. KLH1 and KLH2) in order to "isolate". Because the claim possesses the comprising language, this would reasonably meet the limitations. And it is in this similar analysis that Gebauer et al. do teach an isolated haemocyanin. Gebauer et al. teach the separation of the subunits of KLH2, the limitation of isolation need only be taken from its natural state, or that of whole KLH2, and Gebauer et al. have convincingly performed this task as evidenced by the SDS-Page gel. The issue is not whether a homogeneous mixture of, for instance, domain c (SEQ ID No: 75) has been homogeneously isolated because this limitation is again not in the claim, although a skilled artisan would easily recognize by the SDS-Page gel on p. 58, Figure 4L, that a single band represents a highly purified/homogenous mixture. Gebauer et al. also point to this fact by sequencing the N-terminus of each domain they isolated, and this is presented on p. 59, Table 2. The data presented in this table details N-terminal sequence analysis of the isolated domains from KLH2 which appear on the gels on p. 58. Upon comparing the N-terminal sequences against the ones presented in the claims, specifically SEQ ID Nos: 41 (domain c), 42 (domain d), 71 (domain f), 72

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(domain g) and 73 (domain h), in each instance the isolated domains are missing the first 4-8 amino acids when compared to each of the comparable sequences taught by Applicant. Hence, Gebauer et al. do not teach, for instance, a polypeptide/protein comprising SEQ ID No: 75, but they do teach what appears to be homogeneous domains that are *fragments*, which is a limitation of the claimed invention. In regards to the limitation of claims 32-35, in that the polypeptide is recombinant, in the absence of all other data and limitations (e.g. a glycosylated, fully active polypeptide) the fact that it is recombinantly produced does not necessitate novelty.

New Rejections/Objections

Claim Objections

10. Claims 24, 25, 32-35 and 38-42 are objected to because of the following informalities: The claim is dependent upon a non-elected claim. Applicant is required to rewrite this claim in an independent format. Appropriate correction is required.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 24, 25, 32-35 and 38-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims are drawn to polypeptides of SEQ ID No: 75 and fragments thereof. The claims merely recite that the fragments must possess the same immunological activity as the full length polypeptide. There is no recitation as to what part of the full length polypeptide is essential for this activity and which is therefore conserved. Thus, the claims are drawn to an undefined genus of amino acids with the only potential to recognize them being by sequence identity.

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factors present in the claims are the partial structure thereof. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description.

Vas-Cath Inc. V. Mahurkar, 19USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” As discussed above, the skilled artisan cannot envision the detailed

structures of fragments thereof pertaining to either or both the polypeptide of SEQ ID No: 73, and therefor conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the methods of making the claimed invention. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating or making it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 24, 25, 32-35 and 38-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Harris et al. (Micron. 1995. Vol. 26, No. 3, pp. 201-221). Harris et al. teach the isolation of KLH1 from KLH2 from *Megathura crenulata*, which is the organism that the present invention/polypeptides were isolated (initially) from. Both of these subunits are in their full lengths (e.g. possess all of their domains) and are shown on a native page gel on p. 207, Figure 5. The claims are anticipated because the claim language is open so reads upon the full length KLH2subunit and, by all comparable data, the invention now claimed and the protein of the prior art are the same or equivalent protein because the genus and species of bacteria are identical, the relative

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molecular weight of the protein isolated in the gel is identical. In addition, the protein has the same or equivalent amino acid sequence whether the amino acid sequence is known or not, as the amino acid sequence is an inherent characteristic of a protein or polypeptide.

Conclusion

10. No claim is allowed.

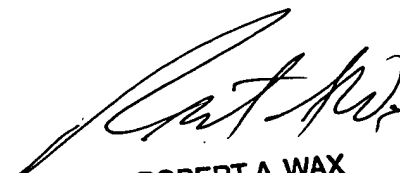
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Noakes, Ph.D. whose telephone number is 571-272-2924. The examiner can normally be reached on Monday to Friday, 7.30am to 4.00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SMN
27 December 2005



ROBERT A. WAX
PRIMARY EXAMINER